DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 5/3/10. Claim(s) 1-11 have been cancelled. Claim(s) 12-22 are pending. Claim(s) 12, 21-22 have been amended. Claim(s) 12-22 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified or repeated below for Applicant's convenience.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-20 of copending Application No. 11/406,296. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are an

obvious variation since both disclose a method of treating lameness in horses by administering bisphosphonic acid derivatives of the same scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Examiner acknowledges Applicant's request that the double patenting rejection(s) be held in abeyance until allowable subject matter is identified.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 12-22 are rejected under 35 U.S.C. 103(a) as being obvious over Barbier et al. (US Patent 5,488,041) in view of Huber et al. (US Patent 3,637,641).

The instant claims are directed to a method of treating lameness caused by osteoarthrosis comprising administering to a non-human animal suffering from osteoarthrosis and not suffering from fractures an effective amount of a bisphosphonic acid derivative selected from claim 12.

Barbier et al. teach promoting bone repair in human and veterinary medicine by administering a therapeutically effective amount of bisphosphonic acid derivative of formula I (abstract). A preferred compound is 4-chlorophenyl thiomethylenebisphosphonic acid (col. 2, line 9). Various salt forms are disclosed including tiludronic acid. The biological effect of bisphosphonic acid derivatives is to inhibit bone resorption by reducing the activity of the osteoclasts (col. 2, lines 25-30). Several bisphosphonic acid derivatives are currently being developed for humans for use in the treatment of bone diseases such as Paget's disease and osteoporosis, which are characterized by an osteoclastic stimulation (col. 2, lines 44-49). The physiological process of bone repair is defined as the successive appearance of different cicatricial tissues in the following order: cartilage, primary bone, and lamellar bone. Each of these is only formed after the destruction of the previous one. Such a change is therefore due to a resorption, which is ensured by macrophagic cells: the chondroclasts for cartilage resorption and the osteoclasts for bone resorption (col. 1, lines 8-15). Barbier et al. teach that these bisphosphonic acid derivatives can be administered orally, parentally, intravenous, transdermally, or by an implant (col. 3, lines 19-21). The daily dosage unit

can comprise from 0.001 mg to 1.2 g of bisphosphonic acid derivative (col. 3, lines 40-42). For an average horse weighing 1000 pounds, this equates to a weight of 453 kg, which further equates to 0.453 mg of active agent at the rate of 0.001 mg/kg as specified in claim 15.

Barbier et al. teach as disclosed above, however, fail to specifically disclose treating lameness in horses suffering from osteoarthrosis.

Huber et al. teach an abnormal bone condition called bony exostosis is common in animals, especially horses. Bony exostosis involves the first, second, and third phalanges, as well as sesamoid bone, cannon bone, and carpal joints. In its various clinical manifestations, it is known as asteoarthritis (or osteoarthritis) of the carpal joints, splits, osselets, sesamoiditis, ringbone, sidebone, and navicular disease (col. 2, lines 10-18). Bony exostosis may be the result of several factors, including hereditary predisposition, faulty nutrition, and conformation, improper shoeing, and traumatism. Initial symptoms include lameness and difficulty in locomotion (limping) followed by enlargements around the effected joint. Some of the bony structural abnormalities are areas of osteoclastic activity (col. 2, lines 35-44).

It is noted that the limitation "caused by osteoarthrosis" in claim 12 is given little patentable weight since the disorder, lameness, is still clinically the same no matter what the etiology or origin of the disorder is.

It is also noted that the method taught by the cited prior art would obviously not involve an increase in bone density being detectable by radiological examination

following treatment since all elemental steps (patient population, active agent, dosage) of the claimed invention have been taught by the cited prior art.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have administered a bisphosphonic acid derivative, for example 4-chlorophenyl thiomethylenebisphosphonic acid, as taught by Barbier et al. to treat lameness in a horse suffering from osteoarthrosis as taught by Huber et al.

A person of ordinary skill in the art would have been motivated to administer a bisphosphonic acid derivative, for example 4-chlorophenyl thiomethylenebisphosphonic acid, as taught by Barbier et al. to treat lameness in a horse suffering from osteoarthrosis as taught by Huber et al. because: (1) Barbier et al. teach broadly that bisphosphonic acid derivatives are useful for treating bone disorders; and (2) Huber et al. teach that bony exostosis, also known as osteoarthrosis, is a common bone disorder in horses characterized by lameness and difficulty in locomotion or limping. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating lameness in horses suffering from osteoarthrosis by administering a bisphosphonic acid derivative, such as 4-chlorophenyl thiomethylenebisphosphonic acid.

Response to Arguments

Applicant argues nonobviousness because the cited prior art references do not teach specifically treating lameness caused by osteoarthritis. Instead, Barbier is directed to a method of bone repair and specifically indicates its methods are to be used following a bone fracture or bone surgery to promote bone repair. Thus, the primary target is bone, whereas the instant invention is directed to the cartilage that is the primary therapeutic in lameness caused by osteoarthritis.

This is not persuasive because, as stated before, the etiology of a particular disease is given little patentable weight. The Examiner's position is that lameness is clinically the same regardless of whether it is osteoarthritis induced or not.

Applicant argues that lameness caused by osteoarthritis differs significantly from other lameness disorders and is a distinct condition with a distinct origin. Specifically, Barbier, which is directed to use of bisphosphonic acid derivatives following bone fractures or bone surgeries, to be useful to treat any form of lameness, much less one that targets a completely different tissue, namely cartilage tissue.

This is not persuasive because Applicant appears to change the scope of the invention. The instant claims are drawn to a method of treating lameness, not a method of treating bone fractures or cartilage lesions. While the symptoms of bone fractures or cartilage lesions may differ, the symptoms of lameness are the same. It is the symptoms of lameness that must be examined.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1627

YSC